October 18, 2023

Arthrex Inc
Jessica Kim
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K232897
Trade/Device Name: Arthrex Small External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: September 14, 2023
Received: September 18, 2023

Dear Jessica Kim:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -S

Lixin Liu, Ph.D
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232897

Device Name
Arthrex Small External Fixation System

Indications for Use *(Describe)*
Arthrex Small External Fixation System is intended to be used in the stabilization of open and/or unstable fractures in anatomies such as the hand, wrist, forearm, foot, and ankle where soft tissue injury may preclude the use of other fracture treatments. The Arthrex Small External Fixation System is intended to be non-weight bearing.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date Prepared	October 18, 2023
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Jessica Kim Title: Senior Regulatory Affairs Specialist Phone: +1 (239) 643-5553 extension 73892 Email: Jessica.Kim@arthrex.com
Trade Name	Arthrex Small External Fixation System
Common Name	Arthrex Small External Fixation System
Product Code	KTT, JDW
Regulation Number	21 CFR 888.3030 21 CFR 888.3040
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class	II
Predicate Device	AOS Small External Fixation System (K141912)
Purpose of Submission	This Special 510(k) premarket notification is submitted to obtain clearance for the Arthrex Small External Fixation System
Device Description	The Arthrex Small External Fixation System is an external fixation device comprised of rods, clamps, and threaded half pins used for the management of bone fractures and reconstructive orthopedic surgery. The Arthrex Small External Fixation System is a modular system designed to provide options in frame construction, simplicity in frame components, and ease of use. The system is comprised of titanium (Ti-6Al-4V ELI conforming to ASTM F136), stainless steel (316L and 304 conforming to ASTM F138 and A276), and Aluminum (6061-T6 conforming to ASTM B211) clamps (pin-to-rod and multi-pin); stainless steel (316L conforming to ASTM F138) threaded half pins; and carbon fiber connector rods. The Arthrex Small External

	Fixation System is manufactured with threaded half pins and rods of 5.0 mm shaft diameter, which allows for support with small, long bone or short bone fractures. The Arthrex Small External Fixation System is a single-use, non-sterile device intended for end-user sterilization. The Arthrex Small External Fixation System is manufactured with pins and rods of 5.0 mm shaft diameter, which allows for connectivity for support of bone fractures. The pin-to-rod clamps are designed to clamp the 5.0 mm carbon fiber rods to the 2.0 mm and 3.0 mm stainless steel threaded half pins, or other rods. The multi-pin clamps are designed to attach to other external fixator pieces to build constructs for a variety of fracture types and allows for angulated pin insertion. The stainless steel threaded pins come in 2.0 mm and 3.0 mm in diameter, and in total lengths of 55 mm, 75 mm, 100 mm, or 140 mm. The thread lengths come in 10 mm, 15 mm, 20 mm, and 25 mm. The threaded pins have twist flutes so that they are self-drilling and self-tapping. The stainless steel Drill Guide Pins are supplied in 1.5 mm diameter. The connecting rods are carbon fiber with an overall diameter of 5.0 mm and are in lengths of 50 mm, 75 mm, 100 mm, 125 mm, 150 mm, 200 mm, 250 mm, and 300 mm.
Indications for Use	Arthrex Small External Fixation System is intended to be used in the stabilization of open and/or unstable fractures in anatomies such as the hand, wrist, forearm, foot, and ankle where soft tissue injury may preclude the use of other fracture treatments. The Arthrex Small External Fixation System is intended to be non-weight bearing.

Performance Data	The Arthrex Small External Fixation System has the same intended use and fundamental technology as the predicate device cleared, K141912. The device is the same design as the predicate device. No design modifications were made to the Arthrex Small External Fixation System and the transition from AOS to Arthrex do not present a new worst case. Therefore, the mechanical testing conducted for the predicate devices still represents worst case testing and additional verification testing are not required for the devices. There has been no change in the device materials or manufacturing materials/process and no other chemicals have been added (e.g., plasticizers, fillers, additives, mold release agents) since the Arthrex Small External Fixation System were originally cleared under the primary predicate, AOS Small External Fixation System, K141912. Additionally, steam sterilization of titanium alloy (Ti-6Al-4V ELI) and Stainless Steel have not shown any evidence of causing bio-compatible or adverse effects. The surface microstructure, chemical composition of alloy, and physical characteristics are not significantly or adversely impacted in any way after being subjected to steam sterilization. Since the characteristics of the solid metal alloy are not significantly impacted by steam sterilization, the biocompatibility of the metal is likewise also not significantly impacted and therefore, no new biocompatibility testing has been provided. The packaging material for the non-sterile devices is polyethylene pouch, commonly used in the medical device industry. The non-sterile devices are to be stored in their original unopened packaging.
Technological Comparison	The Arthrex Small External Fixation System was previously cleared as the AOS Small External Fixation System under K141912. The Arthrex Small External Fixation System is substantially equivalent to the predicate devices cleared under K141912 in which the

	intended use, fundamental scientific technology, design, material, sterility, and shelf-life are identical.
Conclusion	The Arthrex Small External Fixation System is substantially equivalent to the predicate devices cleared under K141912 in which the basic design features and intended use are the same. No device modifications were made to the design. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the device is substantially equivalent to the currently marketed predicate devices.